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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,466	08/16/2001	Larry D. Paskar	39868/25551	3794

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EXAMINER

BOCKELMAN, MARK

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 11/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/931,466

Applicant(s)

Paskar

Examiner

Bockelman

Group Art Unit

3762

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 8-13-02
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-7, 10-16, 19-22 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-7, 10-16, 19-22 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☒ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

DETAILED ACTION

1. The examiner has made a thorough review of the parent application 08/764,745 that was unavailable at the time of the first office action and has the following new grounds of rejections accordingly.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the longitudinal axis of each curve as well as the relative curve features of claim 14 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Priority

3. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 1.53(b) as follows:

The second application must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the second application

must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ 2d 1077 (Fed. Cir. 1994).

It is noted that applicant's original specification in the current application is not identical to that in the parent application 08/764,745 or its preceding parent applications. 37 CFR section 1.53 (5) requires that "Any new change must be made in the form of an amendment to the prior application as it existed prior to the filing of an application under this paragraph. Applicant's original filed specification in the current application has three new paragraphs beginning on page 6, second paragraph. In addition to being improperly filed, the new paragraphs included in the specification contain information regarding the relationships between the curve members that are not readily apparent in the parent application and additionally list new portions of the body to which the combination catheter may be used. In addition, applicant's claims contain new language which support is not readily apparent in the parent application. For instance, the claims now require the outer catheter to be "fixed" in a first curve, the only support for such a configuration is associated with the embodiment shown in figures 15 and 15b. While these figures show an outer curved catheter in a bent configuration it is not readily apparent that the outer curve is fixed in anyway other then simply being bent. In addition, the figure relied upon in support of the current claimed invention, namely 15b, did not explicitly state that the curve shown is part of a method used the body in the parent application, but merely as showing curves that can be formed. Applicant also

calls for a fixing step for forming the inner catheter second curve with respect to the outer catheter curve wherein the original specification appears to have the curve previously "fixed" or preformed, and then inserted into the outer member to provide an out of plane configuration.

Additionally, upon further consideration of the Board's Remand to the Examiner mailed October 26, 2001 and upon their urging on page 4 of that paper, the examiner notes that as stated by the board, the phrase "at least one of said catheter tube and said inner medical element" has a remote control means which goes beyond the scope of the original disclosure in that one, but not both, of the catheter tube and element have a remote control member.

4. This application repeats a substantial portion of prior Application No. 08/764,745, filed 12/12/96, and adds and claims additional disclosure not presented in the prior application. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

Since applicant's original filing was not properly filed for achieving status as a continuing application and also introduces new matter, applicant may either delete the continuity to the parent applications or change the status of the current application to a continuation in part of the 08/764,745 parent application.

Claim Rejections - 35 USC § 112

5. Claims 1-7, 10-16 and 19-22 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that claims fail(s) to correspond in scope with that which applicant(s) regard as the invention can be found in Paper No. 9 filed 8-13-02. In that paper, applicant has stated that the Sylvanowicz catheter does not meet applicant's limitation that the catheter have a "distal end portion fixed in a first curve such that the longitudinal axis of the distal end portion of the catheter defines a plane" since the Sylvanowicz catheter has a straight portion that extends in between the distal tip of the catheter and the curved portion 60 and this statement indicates that the invention is different from what is defined in the claim(s) because the claim does not require that the curve on the distal end of the catheter **start at the distal tip of the catheter and extend rearwardly.**

In addition, if the claim language that applicant argues has such a meaning than applicant has an inadequate written description for the same limitation applied to the inner surgical element when figure 15A of applicant's own specification clearly shows a straight portion 35 at its distal tip despite using the same claim language in reciting the outer catheter member.

6. Claims 1-7, 10-16, 19-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

First, as noted above in item 4 above, applicant argues that the meaning of the phrase "distal end portion fixed in a first curve such that the longitudinal axis of the distal end portion of the catheter defines a plane" refers to catheters with curves that start at the distal tip and extend rearwardly along the tube. However, applicant applies the same language to the inner surgical element which clearly lacks such a structure, thus rendering the meaning of the phrase indefinite if applicant is to insist that the language be construed in such a manner.

Secondly, applicant's independent claims 1, 10 and 19 all recite that the longitudinal axis of the curved portion at the distal end of the catheter defines a plane. As stated in the first office action, an axis is a straight line and a plane can only be defined in terms of lines when at least two lines are specified. If applicant wishes to be their own lexicographer and continue to use the term, the examiner insists that the curved longitudinal axis be shown in the drawings so as to properly define the phrase outside its normal plain and simple language. The examiner again recommends to applicant to recite that the catheter curve lies in a plane. In addition, applicant now recites in claim 1 that the apparatus remains in the specified configuration "during a period of time sufficient to permit medical use of the catheter tube or the inner medical element." It is unclear as to whether applicant intends for this limitation to be an intended use limitation or actual method limitation that results in a hybrid claim which

recites along with the catheter, which includes a method of usage step buried in an apparatus claim. The examiner notes that the latter is an improper combination/subcombination claim since the preamble only sets forth the combination catheter and in addition are considered a hybrid method and apparatus claim has been determined by the courts to be indefinite (See MPEP 2173.05(p) I and II).

7. Claim 6 has a lack of antecedent basis and is thus indefinite in regard to the limitation "said second plane". There is no mention of a second plane either in applicant's preceding claims or in the specification.

8. Claim 19 has a lack of antecedent basis and is thus indefinite in regard to the limitation "*the distal end* of the combination catheter".

9. Claims 1-7, 10-16, 19-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The examiner does not find in the specification as originally filed, a time period or medical procedure associated with figures 15 and 15b, which provide the sole disclosure to that which is being claimed now.

Applicant's claim 19 recites that the combination catheter distal end is out of the plane of the first curve. However, applicant's disclosure only shows the inner catheter to

be out of plane and not both the inner catheter and outer sheath. In addition, the examiner does not find where applicant fixes a first curve in the outer sheath and a second curve for the surgical element for a first procedure followed by a reconfiguration of another curve a second medical procedure.

Claim Rejections - 35 USC § 101

10. Claims 1-7 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Until further clarified, applicant's claims 1-7 are considered to be drafted to both apparatus and method since they recite an apparatus during a specific period of time of a method.. Such Apparatus and methods steps are not considered statutory subject matter. See MPEP 2173.05(p)I and II and Ex Parte Lydell 17 USPQ 2d

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claim Rejections - 35 USC 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1-7, 10-16, 19-22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sylvanowicz USPN 5,267,982 (alone or in view of either Voda USPN 5,445,625 or Weldon USPN 5,195,990 and Cho USPN 5,109,830).

With regard to apparatus claims 1-7 it would appear that applicant in reciting the formation of the out of plane catheter configuration during a particular period of time has formulated the limitation in the claim as a statement of intended use. In this regard, Sylvanowicz teaches an inner catheter illustrated in figure 11 (surgical element) that is situated within an outer catheter figure 10, each with preformed curves. The entire assembly of catheters is to be inserted into the body and Sylvanowicz teaches a element 30 that maybe used to apply an adjustable constricting force against the inner catheter to effect sealing. This of course also applies a friction grip against the inner catheter that would tend to inhibit rotation in an identical fashion as applicant's fixing means shown as element 103 of applicant's specification. Applicant's "intended use" only requires that the reference be capable of forming the configuration at some period of time. Sylvanowicz teaches that with regard to his two different catheter configurations, the configuration in figs 1-8 has in at least one embodiment that is a standard Judkins left coronary catheter structure or a modified left Judkin structure (figs 9-14) wherein the angle defined by bend 62 is slightly larger. The examiner contends that when used as in the same manner as a Judkins left catheter, the assembly of inner and outer catheter provides a planar assembly. The examiner cites Voda USPN 5,445,625 figures 1a -1d as prior figure demonstrating at the time as a standard left Judkins coronary catheter known at the time of the Sylvanowicz filing and notes that the structure demonstrates a planar curve at the bend. The examiner thus concludes that the Sylvanowicz outer sheath possesses a planar configuration prior to insertion into the body. The examiner also concludes that if applicant's apparent method steps in

apparatus claim 1 are view as intended use the Sylvanowicz catheter assembly is fully capable of performing the function. The examiner also notes that if the method steps are considered actual steps performed in the apparatus claim, the examiner still considers the limitation to be met. The examiner also notes that nothing in the Sylvanowicz disclosure suggests that the planar configuration would be compromised in the aortic root region. While the disclosure shows a single point on the catheter that engages the wall of the ascending aorta opposite the left coronary artery, such a single point of contact could not conceivably alter the outer catheter curve in a nonplanar manner. Even if the single point engaged the curved portion orthogonal to the plane of the curve (which it does not), the curve would still lie in a plane although it may no longer contain the proximal segment 52. Since claims 1 does not require any fixing step, the mere rotation of the inner catheter member with respect to the outer catheter member will inherently provide a time of medical use, that is a catheterization of the aorta and its coronary arteries. Applicant's portion of his specification that is dedicated to the out of plane configuration fails to explicitly state any type of medical method for any period of time.

If the applicant's "method" limitations of the apparatus claim 1 are considered to be actual steps performed the examiner considers the Sylvanowicz disclosure to still meet the claims under 35 USC 102, or be obvious under 35 USC 103 for the following reasons:

First, it is apparent that the Sylvanowicz catheter is capable of assuming applicant's out of plane configuration in performing hi catheterization procedure and that

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if not inherent, it is at least obvious from the Sylvanowicz disclosure that such a configuration is within the realm of possibilities within the Sylvanowicz procedure.

Secondly, as noted above, the Sylvanowicz catheter assumes a Judkins left coronary shape while in the configuration of figure 12 which as demonstrated above, would provide curve 60 in a planar state. Inner catheter member 57 would then be either positioned to be aligned in said plane or alternatively be oriented at an angle that would thus meet applicant's method claim. Assuming that it does not already meet applicant's limitation, Sylvanowicz teaches that the inner catheter is rotated with respect to the outer catheter so as align the inner catheter with the right coronary ostia (see column 7 lines 50-65). Thus, at some point, the inner catheter will be "positioned" in an out of plane configuration including when the right coronary ostia has been intubated and sealing gasket while providing a sealing constriction also provides friction so as to fix the inner catheter in place with respect to the outer catheter member. It is impossible for Sylvanowicz to change the combination catheter configuration from figure 12 to that which is shown in figure 14 since Sylvanowicz teaches that only the inner catheter need be rotated (column 7 lines 61-63). Since the examiner considers. On the other hand, Sylvanowicz does not explicitly teach that the inner catheter is "positioned" in a "fixed" manner so that the inner catheter curve is fixed out of plane with respect to the outer catheter as specified in claim.

While the examiner notes that Sylvanowicz does not teach a fixing step, the examiner considers it inherent that the constrictional frictional forces applied to Sylvanowicz to prevent leakage would be sufficient to prevent the inner member from

shifting while attempting to intubate as well as inject dye into each of the coronary arteries. Otherwise it would have been obvious to prevent rotation by tightening the Sylvanowicz sealing gasket after catheter placement as taught by Cho USPN 5,109,830, which uses a similar device for "locking" an inner element after it has been placed at the desired location. The curves in the Sylvanowicz catheter are remotely controllable by moving the inner catheter longitudinally with respect to the outer catheter.

14. Claims 1-7 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Costella USPN 4,696,544 or D'Amelio et al USPN 4,659,195) (each reference alone or in view of Ueda USPN 4,617,914 and US classification 600/148).

Costella teaches an inner element probe and outer guide insertion tube, each of which has a two plane bending assembly (column 8 lines 30-34). Rotable outer insertion tube can be fixed against relative rotation by set screw 23. The picture shows a bent configuration. The examiner considers the intended use statement of the out of plane configuration in applicant's claim 1 to be fully met by Costella, since such a construction allows for such a function to be performed. Because in applicant's arguments filed 8-13-02, applicant stated that "fixed" meant preformed or bent by a wire, the examiner considers Costella to show a fixed configuration. On the other hand, a normal use of the word fixed would seem to suggest that the wire is tension set by some type of mechanical device. In that instance, the examiner considers it to be obvious to include a

brake mechanism within the Costella device to hold the bent configuration when the actuator is release by the physician since such braking mechanisms are well known in the art as demonstrated by Ueda USPN 4,617,914 as well as the US patent classification system 600/148.

D'Amelio et al teaches a similar device as explained in applicant's earlier application 08/764,765 and is fully capable of performing the recited functions since the inner scope and outer scope are each independently bendable and rotatable with respect to one another and can be rotatably fixed with respect to one another. The examiner relies upon the teaches of Ueda for braking the bendable catheter as was applied to Costella above.

15. Claims 1-7, 9-16, 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petruzzi USPN 4,474,174 in view of D'Amelio et al USPN 4,659,195, Ueda 4,617,914 (US Patent class 600/148), Cho USPN 5109,830 and Takahashi reference manual.

Petruzzi et al teach an inner surgical element comprising a catheter with a preformed curve 56 along with a surgical instrument disposed therein, and both further disposed in an outer catheter in the form of a duodenoscope. As was well known in the art, such scoped has a two way control element 42 and 42' that allow two plane bending to traverse the alimentary tract including the small intestine region. If not apparent to one of ordinary skill in the art that Petruzzi et al uses such two plane direction it would have been obvious to D'Amelio et al USPN 4,659,195. As can be seen in figure 1 of

Petruzzi, the device of Petrucci is used to position catheter member 56 into the ampulla of Vater which is located on the rear wall of the duodenum in a highly curved region which tends to curve towards the front of a person near the stomach and back towards the rear as well as to the left side approaching the ileum. This relative location of the ampulla of Vater is shown to some extent by Petrucci but can better be seen in the three dimensional figure attached to this office action (Takahashi "Atlas of the Human Body"). As a result of the relative positions, it is seen as a requirement that the outer tubular member of Petrucci must be used to position the endoscope in a left right manner relative to the page while the catheter 56 is bent and or manipulated to guide its tip into the page so as to access the ampulla of Vater. Such a manipulation requires the inner surgical element 56 60 be positioned out of the plane to the bent curved portion of the outer endoscope. It is apparent to those of ordinary skill in the art that such an out of plane configuration would be necessary in order to access the the ampulla of Vater. In terms of rotationally fixing the inner surgical element, It was well known to stabilize endoscopic devices including rotationally fixing and sealing the inner surgical element relative to the outer sheath body as disclosed by Cho. Petrucci shows a first and second configuration in figure 3 that are used in catheterizing the duodenum and later the ampulla of Vater. The bends in the Petrucci catheter as shown in figure 11 are both within 3 lengths of the smaller radii of curve.

16. Claims 1-7, 10-16 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ganz et al USPN 4,430,083 in view of Sylvanowicz, Cho and

Takahashi page 42 Ganz et al shows in figure 12 and 13, methods for catheterizing two passageways of the lower circumflex branch using a catheter using a planar outer catheter 11a (column 7 lines 7-20) and an inner rotatable catheter 105. The figures 12 and 13 appear to show an out of plane configuration as the inner catheter 105b is shown in rotated position to access each branch. Takahashi is presented as showing how the branches go off in different directions requiring such an out of plane configuration. While Ganz does not teach rotationally fixing the inner catheter, it would have been obvious in view of Cho and Sylvanowicz to provide a sealing as well as locking force to maintain placement of the catheter during drug delivery. The curves on the inner catheter are remotely controllable by rotating and sliding the catheters with respect to each other in a manner as taught by Sylvanowicz or otherwise obvious. The examiner considers it obvious to provide the first treatment of figure 12 followed by a second treatment in figure 13.

17. Claims 1-7, 9-16 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cho USPN 5,109,830 in view of Ueda (class 600/148) and Takahashi (page 66). Cho teaches a method of accessing the various ducts including pancreatic, bile , common etc. and shows such an arrangement in figure 7. While figure 7 shows a duodenoscope 51 having a bent configuration as well as an inner surgical element 3, better seen in figure 6, also having a preformed bend, it is unclear as to whether the duodenoscope has a fixed curve therein. The examiner cites Ueda as showing that it was known to use a braking mechanism to retain or fix curve regions in an endoscope. To have provide the bent configuration of element 51 with a braking

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tension wire would have been obvious to those of ordinary skill in the art particularly as taught by UEDA and the examiner's citation of the class/subclass schedule for 600/148. As can be seen in Takahashi, the gall bladder as well has hepatic duct as well as common bile duct all feed behind the upper colon thereby making it a necessity to form an out of plane configuration to access these members. The examiner considers applicant's claims to be obvious in view of the various configurations of the ducts.

18. Applicant's arguments with respect to claims 1-7, 9-16 and 19-22 have been considered but are moot in view of the new ground(s) of rejection.


19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W Bockelman whose telephone number is (703)-308-2112. The examiner can normally be reached on Monday - Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703)-305-3591 for regular communications and (703)-306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.

MWB

November 1, 2002


MARK BOCKELMAN
PRIMARY EXAMINER